UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,722	05/01/2001	Stanley E. Katz	CSI 1.0-005CIP	8104

7590 09/26/2003

RICHARD R. MUCCINO
758 Springfield Avenue
Summit, NJ 07901

EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/846,722	Applicant(s) Katz et al
	Examiner R.S. Travers J.D., Ph.D.	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 27, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) *19-26* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) *1-18 and 27-31* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The response filed June 27, 2003 has been received and entered into the file.

Claims 1-31 are presented for examination.

Applicant's election with traverse of group I in Paper No. 5 is acknowledged.

The traversal is on the ground(s) that searching all presented inventions would not represent an undue burden to Examiner. This is not found persuasive because the presented inventions encompass a large therapeutic compound group not linked by structure, medicament class or biochemical effect. To search this broad functionally would place an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-26, reading on non-elected subject matter are withdrawn from consideration.

Claims 27-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals & Interferences in *Ex parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303, as to where broad language is followed by "such as" and then narrow language. The Board stated,

a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. In the present instance, claims 27-30 recite the broad recitation sinusitis, and the claim also recites, "and related conditions associated with nasal congestion, which is a narrower statement of the range/limitation. Applicants recitation of the broad range or limitation together with a narrow range or limitation renders independent claim 27 and dependant claims 29-30 properly rejected as indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those situations where "rhinitis", or related conditions would be "prevented". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain those therapeutic regimens employed to effect diseases prevention without undue experimentation. In the instant case, only a limited number of individual situations are disclosed, or envisioned. Examiner notes prevention reads on the absolute relief of disease, and, or, symptomology: a situation rarely seen within the confines of medical practice. In the instant case, provided working examples fail to illustrate even one situation where any one of many envisioned "Rhinitis" , or related conditions are prevented, thereby failing

to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the therapeutic regimens required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on preventing "rhinitis" or related conditions, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 27-30 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 27-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-30 are rendered indefinite by the phrase "preventing" "rhinitis" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Examples of what therapeutic goals would be encompassed in "preventing" "rhinitis" are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those therapeutic situations that were envisioned as encompassed by regimens directed to "preventing" "rhinitis".

Applicant's phrase fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines, or suggest the required "inflammatory mediator" compounds. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "inflammatory mediator" compound examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "inflammatory mediator" compounds, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-6, 12-18 and 31 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-12 and 27-31 are rejected under 35 U.S.C. § 103 as being unpatentable over Pandse et al and Katz, in view of Lindstrom et al and Lueck.

Pandse et al and Katz teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive, and possessing the therapeutic use herein claimed. Possessing these teachings, the skilled artisan would have been motivated to employ these compounds for any anti-inflammatory use, and enjoy a reasonable expectation of therapeutic success. Claims 7-12 and 27-31, and the primary references, differ as to:

1) recitation of salts, or related compounds.

2) the concomitant employment of these medicaments and carriers,

3) nasal administration of the medicaments, and,

4) disclosure of antimicrobial activity of the active agent

Possessing a compound for a therapeutic use, the skilled artisan possesses that compound's analogs, homologs, isomers, salts, acids, esters and bioisosteres for the same therapeutic purpose.

It is generally considered prima facie obvious to combine therapeutic compounds, carriers and excipients each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-inflammatory agents, carriers and excipients. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Lindstrom et al teach the excipients herein claimed as useful in formulating anti-inflammatory medicaments. The skilled artisan see the selection of one or another formulating agent as the simple selection from among obvious alternatives.

Claims 2 and 4-5 specifically requires an nasal pharmaceutical composition. Katz teaches the claimed compounds for treating inflammation in "body cavities and organs ... open to the environment" (see column 6). The skilled artisan would see this teaching as inclusive of nasal passages. Nasal compositions, and the administration of therapeutic compounds nasally, would have been seen as residing in the skilled artisan's purview.

Lueck teaches the active agent polyethylene glycol as possessing antimicrobial activity, thus, inherently possessing the activity claimed.

Claims 10-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Pandse et al, in view of Merck Index.

Pandse et al teaches the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation, viewed by the skilled artisan as immuno-suppressive, and possessing the therapeutic use herein claimed. Possessing these teachings, the skilled artisan would have been motivated to employ these compounds for any anti-inflammatory use, and enjoy a reasonable expectation of therapeutic success. Claims 10-12, and the primary references, differ as to:

1) the recitation of metabolite compounds, and

2) nasal administration of the medicaments.

Merck Index teaches the claimed pyruvate as the degradation product of propylene glycol, motivating the skilled artisan to employ this compound, or its degradation products for the same anti-inflammatory use.

Pandse et al teach the claimed compounds for treating inflammation generally, and not limited to one specific anti-inflammatory use. Possessing this teaching, the skilled artisan would have been motivated to employ the claimed anti-inflammatory compounds for nasal administration and enjoyed a reasonable expectation of therapeutic success, absent information to the contrary. Nasal compositions, and the administration of therapeutic compounds nasally, would have been seen as residing in the skilled artisan's purview.

Claims 13-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Pandse et al and Katz, in view of Lindstrom et al and Lueck, as set forth above, in further view of Hummel et al.

Hummel et al teach oxymetazoline as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating rhinitis, viewed by the skilled artisan as indistinguishable from the use herein claimed. Possessing these teachings, the skilled artisan would have been motivated to employ this compound for any anti-rhinitis use, and enjoy a reasonable expectation of therapeutic success. Claims 13-18, and the primary references, differ as to:

1) the concomitant employment of these medicaments and carriers,

It is generally considered prima facie obvious to combine therapeutic compounds, carriers and excipients each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-rhinitis agents, carriers and excipients. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617